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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,146

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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,146	Applicant(s) SCHOLL ET AL.	
	Examiner BENJAMIN P. BLUMEL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-47, 52-55 and 68 is/are pending in the application.
- 4a) Of the above claim(s) 44, 45, 55 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-43, 46, 47 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 3, 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of invention I and the required species in the reply filed on April 30, 2008 is acknowledged.

Claims 44, 45, 55 and 68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species and invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 30, 2008.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 30, 2008 was filed after the mailing date of the restriction requirement on March 25, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

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requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/699,936, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The limitations of claims 52-54 (protease inhibitor contained with cyclodextrin; cyclodextrin is Captisol; and protease inhibitor is...E64D) are not supported by the disclosure of '936. Therefore, their priority date is that of PCT/US04/36689, which was filed on November 3, 2004.

Specification

The disclosure is objected to because of the following informalities: while the drawing description for figure 5A is provided, the description for figure 5B has been omitted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-43, 46, 47 and 52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of the invention/Breadth of the claims. The claimed invention is drawn to a method for detecting an influenza A virus in a sample, comprising:

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a) providing: i) a sample; ii) cells susceptible to said virus; and iii) the protease inhibitor E64D; b) contacting said cells and said sample in the presence of said protease inhibitor to produce contacted cells, wherein replication of said virus in said contacted cells **is not reduced** relative to replication of said virus in cells not contacted with said protease inhibitor, and wherein replication of a SARS-coronavirus virus in said cells contacted with said protease inhibitor is reduced relative to replication of a SARS-coronavirus in cells not contacted with said protease inhibitor. The protease inhibitor is also contained with Captisol.

State of the prior art/Predictability of the art. Cunningham and Chandran (WO 06/91610) teach that when E64D is incubated with Ebola-zaire virus (a negative stranded RNA virus) and vero cells, greater than 4-fold decrease in viral titer as compared to a negative control (see figure 5A). Therefore, Cunningham and Chandran teach that using the claimed inhibitor actually reduces viral replication.

Working examples. The working example provided involves the analysis of protease inhibitors, Actinonin, Glycyrrhizin and E64 on viral infectivity of R-Mix cell cultures. The viruses tested were influenza A and B, Adenovirus, RSV and Parainfluenza I, 2 and 3 (see table 5 below). However, all of the protease inhibitors reduced influenza, RSV and Parainfluenza 3 viral infectivity, while inhibitor E64 reduced viral infectivity of all viruses tested except for Adenovirus and inhibitor Actinonin reduced viral infectivity of all viruses tested. Therefore, the reductions in viral infectivity would reduce viral replication as compared to viral infection without protease inhibitors.

**Table 5. Number of Infected Foci In R-Mix Cell Cultures Contacted
With a Respiratory Virus in the Presence of a Protease Inhibitor¹**

Virus	Control*	Actinonin			Glycyrrhizin			E64		
	0	40**	20	10	6.08	1.216	0.152	10	5	0.5
FluA	189 ± 012	118	122	171	163	175	218	176	179	174
FluB	455 ± 022	190	260	317	273	402	426	323	328	398
Adeno	863 ± 100	147	383	781	1061	938	766	865	868	904
RSV	116 ± 012	41	64	103	53	103	130	103	115	107
Para1	245 ± 018	160	191	222	295	233	268	207	243	251
Para2	243 ± 012	151	196	220	281	257	265	205	221	223
Para3	142 ± 014	75	104	115	138	149	138	107	99	127

¹Concentration of protease inhibitors is shown in micrograms/ml, * mean of 6 samples; **Evidence of cell toxicity; R-Mix lot 960925.

Amount of experimentation necessary. Additional research is required in order to determine how effective protease inhibitors, such as E64D, are at detecting influenza virus or any other non-positive stranded RNA virus based on non reduction of viral replication since the examples provided show that such an inhibitor does reduce viral replication and the art also shows that using such an inhibitor also reduces viral production.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 contains the trademark/trade name Captisol.

Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a cyclodextrin and, accordingly, the identification/description is indefinite.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648